

NO. 50022-1

**COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON**

KING COUNTY CITIZENS AGAINST FLUORIDATION,
a nonprofit corporation,

Appellant,

v.

WASHINGTON STATE PHARMACY QUALITY
ASSURANCE COMMISSION,
an administrative agency,

Respondent.

BRIEF OF RESPONDENT

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I. INTRODUCTION

King County Citizens Against Fluoridation (Citizens Against Fluoridation) petitioned the State of Washington Pharmacy Quality Assurance Commission (Commission) to adopt an administrative rule declaring that fluoridating substances in drinking water and fluoridated bottled water are drugs based on the statutory definition of “drugs” under RCW 18.64.011(14)(b) and (d), RCW 69.04.009, and RCW 69.41.010(10)(b) and (d). Citizens Against Fluoridation’s rulemaking petition was filed under the Administrative Procedure Act (APA), RCW 34.05.330, and asked the Commission to disregard or distinguish judicial precedent that previously held that fluorides in drinking water were not drugs. Administrative Record (AR) at 0024-25.

In accordance with existing case law, the Commission concluded that fluoridating substances added to drinking water are not drugs and denied the rulemaking petition. In addition, the Commission considered its own statutory authority to support its denial of the rulemaking petition and statutes declaring bottled water to be food and, therefore, not a drug (RCW 69.04.008). AR at 147-48.

Judicial review of an agency decision to deny a petition for rulemaking depends on a party making an extraordinary showing under RCW 34.05.570(4)(c), and requires a showing that the agency decision is

unconstitutional, outside the statutory authority of the Commission, arbitrary or capricious, or taken by unauthorized persons. None of those extraordinary circumstances exists here, where the agency's rejection of the Citizens Against Fluoridation proposal was soundly based on existing case law holding that fluoridation of water is not a drug for purposes of the statutory powers of the Commission. The appellant's remedy lies with the Legislature to change the law, not a court order directing an agency to adopt rules.

II. RESTATEMENT OF THE ISSUES BEFORE THE COURT

1. Are *Kaul* and *Protect Peninsula's Future* controlling case law on the question of whether fluoride added to drinking water is a drug?
2. Did the Citizens Against Fluoridation meet its high burden under RCW 34.05.570(4) of showing that the Commission exceeded its statutory authority when it relied on controlling case law and the statutory framework to deny the petition for rulemaking?
3. Can Citizens Against Fluoridation show that the Commission acted arbitrarily or capriciously in light of controlling case law that supports the Commission's decision not to adopt the proposed rule and the statutory framework that further supports the Commission's decision?

III. COUNTERSTATEMENT OF THE CASE

Citizens Against Fluoridation is a nonprofit organization opposed to the fluoridation of drinking water. In 2015, Citizens Against Fluoridation submitted a petition for a new administrative rule to the Commission under RCW 34.05.330. The petition sought to have fluoride additives and fluoridated drinking water, whether bottled or from a public water system, declared as “drugs” under RCW 69.04, RCW 18.64, and RCW 69.41, making the fluoride additives and fluoridated drinking water subject to the Commission’s regulatory authority. In support of its petition, Citizens Against Fluoridation argued that the additives and fluoridated drinking waters are intended to aid in the prevention or mitigation of dental disease. The actual language submitted by Citizens Against Fluoridation is attached as Appendix 1. AR at 0021-22.

Recognizing that their petition was contrary to existing case law, Citizens Against Fluoridation sought to distinguish the decision in *Kaul v. City of Chehalis*, 45 Wn.2d 616, 625, 277 P.2d 352 (1954). *Kaul* held that fluoridating substances in drinking water are not drugs and that the City’s use of those substances in fluoridating drinking water was not the practice of medicine or pharmacy. AR at 0024-0025. Citizens Against Fluoridation characterized this portion of the *Kaul* decision as dicta, or as

something that the Commission should ignore because it was not fully argued in the original briefing to the Supreme Court. *Id.*; AR at 0046-0089.

The Commission, however, was also aware of *Protect the Peninsula's Future v. Port Angeles*, 175 Wn. App. 201, 215, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013). In that case, this Court did not agree with the Citizens Against Fluoridation's reading of *Kaul*, stating "[b]ecause a holding that fluoridated waters are drugs would have resulted in a different outcome, *Kaul's* statement is not dicta." *Id.*

Citizens Against Fluoridation's rulemaking petition also relied on portions of the definitions of "drugs" in RCW 18.64.011(14), RCW 69.04.009, and RCW 69.41.010(10). AR at 0019-0089. Citizens Against Fluoridation claimed that the federal Food and Drug Administration (FDA) declared fluoridating substances added to drinking water and fluoridated bottled water to be drugs. Clerk Papers (CP) at 100:1-20. Citizens Against Fluoridation argued that the Commission, as the state regulatory authority over drugs, should similarly declare that fluoridating substances added to drinking water and fluoridated bottled water are drugs under state law, based on RCW 18.64.011(14), RCW 69.04.009, and RCW 69.41.010(10). CP at 100-102.

On December 11, 2015, the Commission heard Citizens Against Fluoridation's presentation in support of its petition for rulemaking.

CP at 92-113. At the conclusion of the December 11 proceeding, one of the Commissioners moved to “deny this petition based on the Court of Appeals decision.” CP at 108:12-13. All but one Commissioner voted in favor of the motion. CP at 110:15-25.

After the vote, Citizens Against Fluoridation’s counsel acknowledged the legal basis for the Commission’s action. Counsel explained that the petition for rulemaking is intended to present the question of fluoridating substances being drugs to the courts, saying “there is a problem with *Kaul*. That is why I included all of the *Kaul* briefing and an argument about *Kaul*. But I agree with you that if the Court of Appeals said it, you’ve got to follow them. So this is what you’ve got to do.” CP at 111:22-25, 21:1 (emphasis added).

The Commission issued a letter, memorializing its decision, on January 26, 2016. AR at 0147-48. The Commission also referenced statutes identifying bottled water as “food,” addressing the regulatory authority for “food” and the Commission’s own regulatory authority. *Id.* This is the agency action and record that is now under review.

Citizens Against Fluoridation filed and served a petition for review of the Commission’s denial of its petition for rulemaking in the Thurston County Superior Court. CP at 4-91. Citizens Against Fluoridation asserted that the Commission’s denial exceeded the Commission’s statutory

authority and was arbitrary and capricious, alleging grounds to reverse or remand under RCW 34.05.570(4)(c)(ii) and (iii). *Id.* at 14.

On February 10, 2017, the Thurston County Superior Court affirmed the Commission's denial of Citizens Against Fluoridation's petition for rulemaking. CP at 166-169. The Superior Court decision recognized the precedent established in *Kaul* and affirmed in *Protect the Peninsula's Future* that fluoridating substances added to drinking water are not drugs. Therefore, the denial of the Citizens Against Fluoridation's petition for rulemaking was neither outside the statutory authority of the Commission nor arbitrary or capricious under RCW 34.05.570(4)(c).

Citizens Against Fluoridation filed a Notice of Appeal with this Court, seeking further judicial review of the Commission's denial of its petition for rulemaking. CP at 170-71. Again, Citizens Against Fluoridation relies upon RCW 34.05.570(4)(c)(ii) and (iii) in invoking this Court's jurisdiction.

IV. STANDARD OF REVIEW

As the Court acknowledged in *Northwest Sportfishing Industry Association v. Washington State Department of Ecology*, 172 Wn. App. 72, 90, 288 P.3d 677 (2012), "[a]nyone may petition an agency to request that it adopt, amend, or repeal any rule. RCW 34.05.330(1)." An agency's decision to deny such a petition for rulemaking is subject to judicial review,

but relief will only be granted under the extraordinary grounds identified in RCW 34.05.570(4)(c). *See also, Squaxin Island Tribe v. Wash. State Dep't of Ecology*, 177 Wn. App. 734, 740, 312 P.3d 766 (2013). This Court reviews the agency's actions "by sitting in the same position as the superior court and by applying Washington's Administrative Procedure Act directly to the record that was before [the agency]." *Nw. Sportfishing Indus. Ass'n.*, 172 Wn. App. at 90; *Squaxin Island Tribe*, 177 Wn. App. at 740.

Under the APA, Citizens Against Fluoridation has the burden to prove that the Commission's denial of its petition for rulemaking should be reversed. RCW 34.05.570(1)(a), (b); *Nw. Sportfishing Indus. Ass'n.*, 172 Wn. App. at 90. Here, that requires a showing that the action is outside the statutory authority of the Commission or was arbitrary and capricious. RCW 34.05.570(4)(c)(ii), (iii).

In reviewing any agency action, a court must "avoid exercising discretion that [the] legislature has placed in the agency." *Nw. Sportfishing Indus. Ass'n.*, 172 Wn. App. at 91, *citing Port of Seattle v. Pollution Control Hearings Bd.*, 151 Wn.2d 568, 589, 90 P.3d 659 (2004). "An agency is accorded 'wide discretion' when deciding to forego rulemaking." *Id.*; *Squaxin Island Tribe*, 177 Wn. App. at 742. A court must give appropriate deference to the "'specialized knowledge and expertise of an administrative agency.'" *Nw. Sportfishing Indus. Ass'n.*, 172 Wn. App.

at 91, citing *Dep't of Ecology v. PUD No. 1 of Jefferson County*, 121 Wn.2d 179, 201, 849 P.2d 646 (1993); *Squaxin Island Tribe*, 177 Wn. App. at 742.

This Court reviews questions of law de novo. *Estate of Ackerley v. Wash. Dep't of Revenue*, 187 Wn.2d 906, 909, 389 P.3d 583 (2017).

To show that agency action is arbitrary and capricious, Citizens Against Fluoridation must show “it is willful and unreasoning and taken without regard to the attending facts or circumstances.” *Rios v. Wash. Dep't of Labor & Indus.*, 145 Wn.2d 483, 501, 39 P.3d 961 (2002), citing *Hillis v. Dep't of Ecology*, 131 Wn.2d 373, 383, 932 P.2d 139 (1997). “Where there is room for two opinions, an action taken after due consideration is not arbitrary and capricious even though a reviewing court may believe it to be erroneous.” *Id.* “Judging whether an agency’s decision was arbitrary and capricious involves evaluating the evidence considered by the agency in making its decision.” *Children’s Hosp. & Med. Ctr. v. Wash. State Dep't of Health*, 95 Wn. App. 858, 871, 975 P.2d 567 (1999).

Citizens Against Fluoridation has not carried its burden and the Commission’s denial of its petition for rulemaking should be affirmed.

V. ARGUMENT

A. The Supreme Court and Court of Appeals Decided Fluoridating Substances Added to Drinking Water Are Not Drugs

In *Kaul*, the Supreme Court held that fluorides in public drinking water are not drugs. *Kaul*, 45 Wn.2d at 625. Mr. Kaul claimed that the City of Chehalis was engaged in “selling drugs, practicing medicine, dentistry, or pharmacy as defined by statute.” *Id.* The Court “considered these assignments of error” and held “they are not well taken.” *Id.*

More recently, this Court confirmed that the statement in *Kaul* was not dicta, rather, it was a holding of the case, once again affirming that fluoridating substances added to drinking water are not drugs. *Protect the Peninsula’s Future*, 175 Wn. App. at 215.

In *Kaul*, the Supreme Court interpreted the laws on drug distribution and the practice of medicine, dentistry and pharmacy in the context of fluoride in drinking water in affirming the trial court’s decision. As said in *Pierson v. Hernandez*, 149 Wn. App. 297, 305, 202 P.3d 1014 (2009), “[w]hen an interpretation of a statute is essential to a judicial decision, it is not dicta.” See *City of W. Richland v. Dep’t of Ecology*, 124 Wn. App. 683, 692, 103 P.3d 828 (2004). Furthermore, “where a decision rests on two or more grounds, none can be relegated to the category of obiter dictum.”

Woods v. Interstate Realty Co., 337 U.S. 535, 537, 69 S. Ct. 1235, 93 L. Ed. 1524 (1949).

Kaul and *Protect the Peninsula's Future* decisions are binding precedent on the question of whether fluoridating substances added to drinking water are drugs regulated by the Commission under RCW 18.64, RCW 69.04, and RCW 69.41. The Commission is bound by decisions of the Supreme Court and the Courts of Appeals on the application and interpretation of the laws the Commission administers. *1000 Va. Ltd. P'ship v. Vertecs Corp., et al.*, 158 Wn.2d 566, 578, 146 P.3d 423 (2006); *State v. Gore*, 101 Wn.2d 481, 487, 681 P.2d 227 (1984); *Godefroy v. Reilly*, 146 Wash. 257, 262 P. 639 (1928). In any event, the Commission is not arbitrary or capricious when it follows existing precedent and declines an individual's suggestion that they disagree with controlling case law.

Under these circumstances, the Commission acted within its statutory authority in denying Citizens Against Fluoridation's petition for rulemaking. The rule proposed in the petition for rulemaking depends on an interpretation of statute contrary to appellate court decisions. Because the denial of the petition was based on binding appellate decisions, it is not unreasonable, arbitrary, or capricious.

B. The Denial of Citizens Against Fluoridation's Petition Is Consistent With the Commission's Statutory Authority

The Supreme Court's decision in *Kaul*, 45 Wn.2d at 625, that fluoridating substances added to drinking water are not drugs continues to apply to all of the statutory definitions of "drugs" in RCW 18.64.011(14), RCW 69.04.009, and RCW 69.41.010(10) upon which the petition for rulemaking relied. To bypass this, Citizen Against Fluoridation cites phrases in the definition of "drugs" in RCW 18.64.011(14), RCW 69.04.009, and RCW 69.41.010(10) to claim that fluoridating substances used in drinking water and fluoridated bottled water are nonetheless "drugs" subject to the Commission's authority. Appellant's Brief (App. Br.) at 13-15. Citizens Against Fluoridation errs because it does not address the context of that defined term in RCW 18.64, RCW 69.04, and RCW 69.41.

When interpreting statutes, the "goal is to determine the legislature's intent by giving effect to the plain meaning of the statute, gleaned both from the words of that statute *and those in related statutes.*" *Estate of Ackerley*, 187 Wn.2d at 910 (emphasis added). "Courts must construe a legislative act as a whole. Whenever, possible, a court should harmonize the provisions of an action to insure its proper construction."

Alpine Lakes Protection Soc. v. Wash. State Dep't of Ecology, 135 Wn. App. 376, 390, 144 P.3d 385 (2007).

Statutory definitions cannot be read in isolation, outside the context of the legislation. The legislation must be read as a whole to understand the statutory regulatory scheme of the act to which those definitions apply. As stated in *Muckleshoot Indian Tribe v. Washington Department of Ecology*, 112 Wn. App. 712, 721, 50 P.3d 668 (2002), “[a] court does not glean the meaning of a particular word from that word alone, but rather from the Legislature’s intent within the statute as a whole.”

In its petition for rulemaking, Citizens Against Fluoridation cited RCW 69.04.009¹, which was the only statutory definition of “drugs” in place when *Kaul* was decided in 1954. RCW 69.04.009 was amended in 2009, but only to change the word “man” to the gender-neutral term “human being.” See Laws of 2009, ch. 549, § 1018 attached as Appendix 2. Thus, the substantive meaning and effect of RCW 69.04.009 remained unchanged from the 1945 version, in place at the time *Kaul* was decided by the Washington Supreme Court.

¹ The Commission also cited to RCW 69.04.008 in its letter denying the petition for rulemaking. AR at 0148. RCW 69.04.008 defines “food” as “(1) articles used for food or drink for people or other animals, (2) bottled water” The definition of “drug” in RCW 18.64.011(14)(c), RCW 69.04.008(3) and RCW 69.41.010(10)(c) excludes “food.”

RCW 69.04.009 defines “drug” to mean:

(1) Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals; and (3) articles (other than food) intended to affect the structure or function of the body of human beings or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

The definition of “drug” in RCW 69.04.009 is substantially the same as the definitions of “drug” in RCW 18.64.011(14) and RCW 69.41.010(10), both of which were enacted after the *Kaul* decision.² Therefore, the holdings in

² RCW 18.64.011(14) defines “drugs” as:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States; (b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals; (c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or (d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

RCW 69.41.010(10) defines “drug” as:

(a) Substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; (b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals; (c) Substances (other than food, minerals, or vitamins) intended to affect the structure or any function of human beings or animals; and (d) Substances intended for use as a component of any article specified in (a), (b), or (c) of this subsection. It does not include devices or their components, parts, or accessories.

Kaul and Protect the Peninsula's Future applies to the definition of “drug” in these later enacted statutes.

Citizens Against Fluoridation incorrectly asserts that the Commission is the agency deciding whether a substance is a drug in intrastate commerce. App. Br. at 12. The only laws addressing the process for the **intrastate** recognition of a “new drug” in intrastate commerce are RCW 69.04.570 through RCW 69.04.640. The agency with the authority to decide whether a product is a “new drug” is the director of the Washington State Department of Agriculture (WSDA), not the Commission. RCW 69.04.580.

Citizens Against Fluoridation did not petition the WSDA Director, nor did Citizens Against Fluoridation submit any evidence or claim that the fluoridating substances or fluoridated bottled water are produced and restricted to sale and use only intrastate. In addition, at the administrative proceeding on December 11, 2015, Citizens Against Fluoridation argued that the Commission should declare fluoridating substances and fluoridated bottled water to be drugs based on a claim that the Food and Drug Administration (FDA) affirmatively stated these substances are drugs. CP at 100-101. Since Citizens Against Fluoridation is relying in part on the alleged position of the FDA on these substances, the petition for rulemaking must be based on interstate sales and use.

Citizens Against Fluoridation's reliance on the alleged position of the FDA in submitting its petition for rulemaking to the Commission is misplaced. Citizens Against Fluoridation assumes the Commission has the same legal authorities as the FDA, except within the boundaries of this state. This assumption is wrong.

The FDA has the exclusive authority to approve a new drug through a new drug application process if that drug will be introduced into interstate commerce. 21 U.S.C. § 355; *Mutual Pharm. Co., Inc. v. Bartlett*, ___ U.S. ___, 133 S. Ct. 2466, 2470-71, 186 L. Ed. 2d 607, 81 USLW 4538 (2013); *United States v. Generix Drug Corp.*, 460 U.S. 453, 461, 103 S. Ct. 1298, 75 L. Ed. 2d 198 (1983). The Commission has no similar authority granted to it by the Washington Legislature. While RCW 18.64.011(14) defines drugs, no statute in RCW 18.64 authorizes the Commission to approve or recognize a substance as a drug. The Commission's primary authority in RCW 18.64 is to regulate the practice of pharmacy, pharmacists, and businesses distributing and manufacturing drugs in the state of Washington by requiring licensure and taking action against the licenses for violations of the laws regulating drugs. RCW 18.64.005.

Under RCW 69.41.075, the Commission is authorized to identify which drugs are to be dispensed only on prescription or are restricted to use by practitioners only. These types of drugs are categorically known as

legend or prescription drugs. The Legislature authorized the Commission to identify legend drugs by “incorporate[ing] in its rules lists of drugs contained in commercial pharmaceutical publications by making specific reference to each such list and the date and edition of the commercial publication containing it.” RCW 69.41.075.

The Commission adopted WAC 246-883-020(2), which states: “For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2009 edition of the *Drug Topics Red Book*.” Citizens Against Fluoridation offered no evidence and made no claims that fluoridating substances in drinking water or fluoridated bottled water are listed as legend drugs in the 2009 edition of the *Drug Topics Red Book*. In fact, when asked by one of the Commissioners if Citizens Against Fluoridation was asking the Commission to recognize these substances and fluoridated drinking water as legend drugs, Citizens Against Fluoridation stated, “Just to clarify, this proposal, the proposed rule is not about legend drugs. It doesn’t mention legend drugs at all. It just says that – and it says that if you make a claim, the rule says, the proposed rule say that if you claim that your fluoridated water or your fluoridation chemicals are intended to prevent tooth decay disease, then it’s a drug under state law. Just a drug under state law.” CP at 104: 22-25, 105: 1-25, 106: 1-3.

Citizens Against Fluoridation also assumes that the Commission has authority to regulate or prohibit the marketing of products making claims that the products will treat or prevent disease. CP at 45-46, 106; App. Br. at 36-45. Unlike the FDA, the Commission does not have statutory authority to regulate or prohibit marketing of products that claim to treat or prevent diseases. By virtue of 21 U.S.C. §§ 331 and 337(a), the FDA was granted the authority to regulate, including prohibiting, any commercial product (food or drug) representing that it is curative or preventive of disease without having obtained approval through the new drug approval process in 21 U.S.C. § 355. The Commission has no such authority.

The Commission's denial of the rulemaking petition is consistent with the Commission's statutory authority. If the Commission had granted the petition for rulemaking, it would have exceeded its statutory authority because the Commission does not have the authority to declare a substance a drug based on its marketing representations as curative or preventive of a disease. The Commission also does not have the statutory authority to declare a substance a drug under RCW 18.64, RCW 69.04, or RCW 69.41.

VI. CONCLUSION

The Commission's final action, denying the petition for rulemaking, properly based its decision on binding case law in *Kaul v. City of Chehalis*, 45 Wn.2d 616, 277 P.2d 342 (1954), and *Protect the Peninsula's Future v.*

Port Angeles, 175 Wn. App. 201, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013).

When Citizens Against Fluoridation's petition is considered in the context of the Commission's statutory authorities, the denial of the petition for rulemaking is consistent with those authorities.

The Commission's denial is well-reasoned under the facts and circumstances. Citizens Against Fluoridation has not carried its burden of establishing that the Commission's denial of its rulemaking petition should be reversed under RCW 34.05.570(4)(c)(ii) or (iii).

The Commission requests that its denial of Citizens Against Fluoridation's petition for rulemaking be affirmed.

RESPECTFULLY SUBMITTED this 9th day of August 2017.

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PROOF OF SERVICE

I certify that I served a copy of this document and Declaration of
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I certify under penalty of perjury under the laws of the state of
Washington that the foregoing is true and correct.

DATED this 9th day of August 2017, at Olympia, Washington.



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APPENDIX 1

Appendix 1

Rulemaking Language Proposed

By Citizens Against Fluoridation

(1) Fluoridation chemical additives (whether or not certified under NSF/ANSI Standard 60) and fluoridated drinking waters (bottled and/or from public water systems, that are fluoridated with such additives) are drugs pursuant to RCW 18.64.011(12), 69.04.009, and 69.41.010(9) when the intended use is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities).

(2) Fluoridation chemical additives include:

- (a) Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
- (b) Sodium Fluorosilicate (aka Sodium Silicofluoride).
- (c) Sodium Fluoride.
- (d) Calcium Fluoride.

(3) It is presumed that the intended use of such additives and such fluoridated drinking waters is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities).

(d) The pharmacy quality assurance commission has jurisdiction to ensure that distribution, wholesaling, and manufacturing of fluoridation chemical additive drugs and fluoridated water drugs in this state provide for the protection and promotion of the public health, safety and welfare.

AR 0021-0022.

APPENDIX 2

limitation is effective with respect to the carrier's liability for conversion to its own use.

(3) Reasonable provisions as to the time and manner of presenting claims and instituting actions based on the shipment may be included in a bill of lading or tariff.

Sec. 1018. RCW 69.04.009 and 1945 c 257 s 10 are each amended to read as follows:

The term "drug" means (1) articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in ~~((man))~~ human beings or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of ~~((man))~~ human beings or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

Sec. 1019. RCW 69.04.010 and 1945 c 257 s 11 are each amended to read as follows:

The term "device" (except when used in RCW 69.04.016 and in RCW 69.04.040(10), 69.04.270, 69.04.690, and in RCW 69.04.470 as used in the sentence "(as compared with other words, statements, designs, or devices, in the labeling)") means instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in ~~((man))~~ human beings or other animals; or (2) to affect the structure or any function of the body of ~~((man))~~ human beings or other animals.

Sec. 1020. RCW 69.04.024 and 1963 c 198 s 11 are each amended to read as follows:

(1) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance generally is recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958; through either scientific procedures or experience based on common use in food) to be unsafe under the conditions of its intended use; except that such term does not include; (a) a pesticide chemical in or on a raw agricultural commodity; or (b) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or (c) a color additive.

(2) The term "safe" as used in the food additive definition has reference to the health of ~~((man))~~ human beings or animals.

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